DEPARTMENT OF HEALTH AND HUMAN SERVICES

(HFI-35)

Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513)-679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 99-362

August 19, 1999

Certified Mail
Return Receipt Requested

Vernon J. Hershberger. M.D.
Medical Director
Family Medical Services
880 Mull Ave.
Akron, OH 44313

Facility I.D.#: 176529

Dear Dr. Hershberger:

A representative from the state of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on August 2, 1999.This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following **repeat** Level 2 finding at your facility:

- Your facility records did not demonstrate that the interpreting physician, [redacted] meet the continuing education requirement of having completed a minimum of fifteen (15) CME credits in mammography in a 36 month period.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identify a failure to meet a significant MQSA requirement and indicate failure by your facility to implement permanent correction of problem found during your previous inspection.

Because the condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of

your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. The Level 2 finding is:

Your facility has no written procedure for handling consumer complaints.

The other item listed in your August 2, 1999 inspection report identified, as Level 3 should also be corrected. We will verify correction of the item during our next inspection. You are not required to address the Level 3 item in your written response.

It is necessary for you to act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations; and
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

Henry L. Fielden
District Director

c. OH/NManubay